Reviva Pharmaceuticals Provides Update on Clinical Development Pipeline

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Enrollment remains on pace for Reviva's Phase 3 clinical trial for the treatment of schizophrenia at 15 sites across the US with enrollment set to begin at sites in Europe and India in Q3 2022

More than 20% of the approximately 400 patients planned for Phase 3 trial already enrolled

Reviva anticipates initiating two Phase 2a trials targeting ADHD and Pulmonary Arterial Hypertension in Q4 2022

CUPERTINO, Calif., July 27, 2022 (GLOBE NEWSWIRE) -- Reviva Pharmaceuticals Holdings, Inc. (NASDAQ: RVPH), a clinical-stage pharmaceutical company developing therapies that seek to address unmet medical needs in the areas of central nervous system (CNS), cardiovascular, metabolic, and inflammatory diseases, is pleased to provide an update on key milestones related to its clinical development pipeline.

Phase 3 RECOVER Study

Reviva's pivotal Phase 3 study and a long-term safety trial to assess Reviva's new chemical entity brilaroxazine for the treatment of subjects with an acute exacerbation of schizophrenia is actively enrolling patients across all sites in the US and remains on schedule to begin enrollment at trial sites in Europe and India during the third quarter of 2022.

The global Phase 3 trial, known as RECOVER, is a randomized, double-blind, placebo-controlled, multicenter study designed to assess the safety and efficacy of brilaroxazine over 4 weeks in approximately 400 patients with acute schizophrenia compared to placebo and a 52-week open-label study will further evaluate the long-term safety and tolerability of brilaroxazine in patients with stable schizophrenia. Brilaroxazine will be administered at fixed doses of 15 mg or 50 mg once daily for 4 weeks in the double-blind part of the study and 15 mg to 50 mg flexible dose once daily for 52 weeks in the open-label part of the study. Since Reviva initiated its first clinical site in Bentonville, Arkansas, led by principal investigator Dr. Fayz A. Hudefi, M.D., at the end of January, the team has initiated 15 geographically diverse sites across the US.

"We have already enrolled more than 20 percent of the patients for this pivotal study," said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. "Based on the positive data reported from our Phase 2 study, we believe brilaroxazine has the potential to address major unmet medical needs and pharmacoeconomics challenges associated with current treatments."

RECOVER Phase 3 Trial Underpinned by Positive Phase 2 Data

In its randomized, double-blind, placebo-controlled, multicenter Phase 2 trial to assess the safety and efficacy of brilaroxazine in 234 subjects with acute exacerbation of schizophrenia or schizoaffective disorder, brilaroxazine met its primary endpoint, which was reduction in total Positive and Negative Syndrome Scale (PANSS) at the end of the treatment from baseline versus placebo. The drug candidate also met all safety endpoints including clinical, labs, body weight, prolactin, lipids, fasting glucose, and EKG. The PANSS total score was reduced by 20 points, a statistically significant treatment difference from the placebo. Brilaroxazine also mitigated positive symptoms and negative symptoms, and improved social functioning and cognition. Importantly, the FDA has agreed to consider a potential 'Superior Safety' label claim, if there is a positive outcome on a relevant endpoint in the pivotal Phase 3 clinical study in schizophrenia currently underway.

Schizophrenia affects approximately 3.5 million people in the U.S. and 24 million globally, yet there are currently no therapies that adequately address the complex mix of symptoms, mood, and cognitive impairment associated with schizophrenia.

In addition to the suboptimal efficacy of current antipsychotic treatments, patients also suffer from side effects and poor tolerability, including akathisia, weight gain/obesity, diabetes, high cholesterol, hypothyroidism, and sexual dysfunction. Moreover, the Company estimates discontinuation/non-compliance rates at 30% to 45% in the acute phase treatment and up to 74% in the long-term treatment of stable schizophrenia patients.

Reviva's Phase 2 data showed that brilaroxazine potentially can mitigate the negative side effects of current treatments which could ultimately improve patient's compliance to the treatment. Reviva has published several research papers on the results of brilaroxazine's pharmacology and the clinical Phase 1 and Phase 2 studies in peer reviewed journals (https://revivapharma.com/publications/).

Top-line data from the RECOVER trial is expected in mid-2023.

Protocols for Phase 2a Studies in ADHD and PAH in Development

Reviva is currently developing Phase 2a trial protocols for studies of brilaroxazine in attention deficit hyperactivity disorder (ADHD) and pulmonary arterial hypertension (PAH) and anticipates initiating the Phase 2a studies in Q4 2022. The addressable market for ADHD is expected to reach $29.3 billion globally by 2028, and the addressable market for PAH is expected to reach $11 billion globally by 2030. Reviva has been granted Orphan Drug Designation for brilaroxazine for the treatment of PAH.

"While we plan to prioritize our efforts on schizophrenia in the near-term, Reviva is evaluating opportunities in additional chronic neuropsychiatric and pulmonary indications that arise from an underlying dysfunction in serotonin and dopamine signaling," added Dr. Bhat. "We believe Brilaroxazine has therapeutic potential in indications related to bipolar disorder, major depressive disorder (MDD), attention deficit hyperactive disorder (ADHD), pulmonary arterial hypertension (PAH) and idiopathic pulmonary fibrosis (IPF) and we remain active in seeking various non-dilutive financing opportunities, including partnerships, to explore these additional indications."

About Brilaroxazine (RP5063)
Brilaroxazine (RP5063) is a new chemical entity with potent affinity and selectivity against key serotonin and dopamine receptors implicated in schizophrenia and other psychiatric disorders. In a multinational, multicenter, double-blind Phase 2 study in 234 patients with acute schizophrenia or schizoaffective disorder, brilaroxazine met its primary endpoint, reducing Positive and Negative Syndrome Scale (PANSS) total score and demonstrating statistically significant improvements for secondary endpoints evaluating social functioning, and positive and negative symptoms. A full battery of regulatory compliant toxicology and safety pharmacology studies has been completed for brilaroxazine. In this completed Phase 2 study, brilaroxazine met all safety endpoints with no weight gain, no increase in blood sugar and lipids, and no cardiac or endocrine adverse effects compared to placebo. The U.S. Food and Drug Administration (FDA) has agreed to consider a potential 'Superior Safety' label claim if there is a positive outcome on a relevant endpoint in a pivotal Phase 3 study in patients with schizophrenia. Additionally, the Company believes brilaroxazine has the potential to delay disease progression in PAH and IPF. Brilaroxazine has already received Orphan Drug Designation by the U.S. FDA for the treatment of these conditions. To learn more about the clinical and preclinical data available for brilaroxazine, please visit revivapharma.com/publications.

About Reviva
Reviva is a clinical-stage biopharmaceutical company that discovers, develops and seeks to commercialize next-generation therapeutics for diseases representing unmet medical needs and burdens to society, patients, and their families. Reviva's current pipeline focuses on the central nervous system, respiratory and metabolic diseases. Reviva's pipeline currently includes two drug candidates, RP5063 (brilaroxazine) and RP1208. Both are new chemical entities discovered in-house. Reviva has been granted composition of matter patents for both RP5063 and RP1208 in the United States (U.S.), Europe, and several other countries.

Forward-Looking Statements
This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical and regulatory timelines and expenses, market opportunity, ability to raise sufficient funding, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential, "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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